Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Keyhole surgery to repair a faulty mitral valve

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice. This leaflet is about when and how keyhole surgery can be used in the NHS to treat people with a faulty mitral valve. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe faulty mitral valves or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on page 7.

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What has NICE said?

This procedure can be offered routinely as a treatment option for people with faulty mitral heart valves, provided that doctors are sure that:

- the patient understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored.

The operation is difficult to perform, so NICE has recommended that surgeons should have special expertise and specific training in performing heart operations using this type of keyhole surgery. Until they are expert, surgeons should carry out this procedure with an experienced mentor.

This procedure may not be the only possible treatment to repair a faulty mitral valve. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Keyhole surgery to repair a faulty mitral valve

The procedure is not described in detail here – please talk to your specialist for a full description.

The heart has four valves that keep blood moving in the correct direction around the body. Oxygen-rich blood flows from the lungs and through the mitral valve into the heart's main pumping chamber, the left ventricle. When the heart squeezes, the mitral valve closes so blood does not flow backwards into the lungs.

Sometimes, the mitral valve stops working properly. It may leak, allowing blood to flow backwards into the lungs. This causes shortness of breath and, eventually, heart failure (when the heart cannot pump enough blood to meet the body's needs). Less commonly, the mitral

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valve may not open properly and this can prevent blood from flowing into the heart from the lungs, again causing breathlessness and heart failure.

Traditionally, repair or replacement of the mitral valve is done by open surgery, which involves cutting into the chest to get to the heart. There may be a long recovery time because the separated bone needs to heal.

In keyhole surgery, small cuts are made in the chest wall between the ribs. A camera and monitor are inserted through one of the cuts. By watching what is happening on the monitor, the surgeon performs the operation to repair the mitral valve using special instruments inserted through the remaining holes. The medical name that your healthcare professionals may use is thoracoscopic surgery.

Both open surgery and keyhole surgery are carried out under general anaesthesia. A bypass machine does the work of the heart and lungs while the heart is stopped during the operation.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks keyhole surgery to repair a faulty mitral valve is a suitable treatment option for you, they should still make sure you understand the benefits and risks before asking you to agree to it.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at eight studies on this procedure.

How well does the procedure work?

In one study of 449 patients, the procedure was successful in 318 out of the 327 patients whose valve was repaired, and in all 122 patients whose valve was replaced.

Four studies looked at how much blood leaked through the mitral valve, using a score where 0 was no leakage and 4 was severe leakage. In the first study 62 patients had valve repair. By 3 years after the procedure, the average leakage had decreased from 3.1 to 0.4. In the second study, 215 patients had valve repair. By 1 year after the procedure, the average leakage had decreased from 4 to 0 or 1 in 201 of the patients. In two further studies involving a total of 234 patients who had valve repair or replacement, immediately after the procedure 205 of the patients had a leakage score of 0.

Three studies involving a total of 677 patients showed that there was an improvement in patients' symptoms of heart failure after the procedure, with the majority of patients having only mild symptoms of heart failure.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the aims of the procedure are survival, success in repairing or replacing the valve, pain after the operation, length of the procedure, length of stay in intensive care, return to normal activities, need for blood transfusion, cosmetic appearance and the need for any further unplanned procedures.

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Risks and possible problems

In four studies involving a total of 1755 patients, 58 patients died before discharge from hospital. In a further three studies involving a total of 1177 patients, 13 patients died within a month of the procedure.

In five studies involving a total of 2357 patients, 98 patients had to have another operation to solve problems with bleeding.

The most common problem after the procedure was an irregular heartbeat. In a large study of 1059 patients, about 10% developed an irregular heartbeat (atrial fibrillation) for the first time after the procedure. In three other studies, involving a total of 671 patients, 54 patients developed an irregular heartbeat.

The studies also looked at whether the keyhole procedure had to be converted to open surgery. In six studies involving a total of 2440 procedures, 66 were converted to an open procedure. One of these studies included 252 patients who had a slightly different procedure.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that possible complications include a tear in the wall of the aorta, blood loss, heart attack, stroke, heart failure, kidney failure, lung injury and death.

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More information about faulty heart valves

Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see <u>www.nice.org.uk/aboutguidance</u>

This leaflet is about 'Thoracoscopically assisted mitral valve surgery'. This leaflet and the full guidance aimed at healthcare professionals are also available at www.nice.org.uk/IPG245

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1435).

National Institute for Health and Clinical Excellence

MidCity Place, 71 High Holborn, London, WC1V 6NA; www.nice.org.uk

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